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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS DEBRA AND JAMES
TINLIN'S SUPPLEMENTAL
STATEMENT OF FACTS IN
OPPOSITION TO BARD'S MOTION FOR
SUMMARY JUDGMENT**

(Assigned to the Honorable David G.
Campbell)

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order No. 53 (Doc. 5770), Plaintiffs Debra Tinlin and James Tinlin (collectively "Plaintiffs") respectfully submit this Supplemental Statement of Facts in Support of their Opposition to Bard's Motion for Summary Judgment.¹

1. Ms. Tinlin believed her filter was placed permanently. (Ex. 1, Debra Tinlin Dep. Tr., 89:16-90:3; 104:15-105:10, Feb. 8, 2017.)

2. No information negative about the Recovery filter was relayed to Ms. Tinlin before the filter was placed in her. (*Id.* at 93:14-22.)

¹ Plaintiffs' Omnibus Statement of Facts, filed October 2, 2017, ECF 7950, is incorporated by reference herein.

1 3. If she had been given the choice, Ms. Tinlin would have opted for a
2 permanent filter. (*Id.* at 169:20-170:2.)

3 4. Ms. Tinlin was born on March 6, 1964. (*Id.* at 36:13-14.)

4 5. Ms. Tinlin was born in a small town in Wisconsin, has lived in Wisconsin
5 for her whole life, and currently resides in the town of Bonduel. (*Id.* at 35:20-36:12.)

6 6. Ms. Tinlin has a husband, Jim, who she has been married to since 1984. (*Id.*
7 at 37:22-38:1.)

8 7. Ms. Tinlin has one son, Andrew, who is currently 28 years old. (*Id.* at
9 38:19-39:1.)

10 8. Ms. Tinlin was implanted with a Bard Recovery filter on May 7, 2005. (Ex.
11 2, Debra Tinlin Dep., Exh. 4.)

12 9. On June 10, 2013, Ms. Tinlin was brought to the ER, diaphoretic and
13 hypotensive, and was diagnosed with cardiac tamponade, cardiogenic shock, multi-organ
14 system failure (including respiratory failure, circulatory failure, liver failure, renal failure,
15 and complex metabolic derangement specifically hyperkalemia) and delirium. It was
16 discovered that the filter had fractured and two struts had embolized to the right ventricle,
17 causing a massive pericardial effusion around the heart with significant compression of
18 the ventricles. She underwent emergent surgical drainage of 600mL of bloody effusion
19 with drain placement but the struts could not be located. After ten days, she was
20 discharged in improved condition, but removal of the fractured struts from her right
21 ventricle was not attempted due to her critical status. (Ex. 3, Debra Tinlin Dep., Exh. 3, at
22 5 (referencing medical records).)

23 10. On July 31, 2013, a fractured strut was successfully removed through open
24 heart surgery and Ms. Tinlin reported feeling better. (*Id.*)

25 11. On August 7, 2013, a follow -up chest CT demonstrated the filter in stable
26 position with seven struts (not the original eight), and several of the remaining seven
27 struts were seen projecting outside the lumen of the vena cava. A single 5mm retained
28 foreign body was seen in the basilar interventricular septum. (*Id.*)

1 12. The filter remains implanted, but Ms. Tinlin was advised in December 2015
2 that there are several pieces of wire in her upper and lower lungs, which are believed to be
3 broken down pieces of the filter, possibly pieces of a second strut, as two pieces were
4 originally reported to be seen in the heart but only one was removed. (*Id.*)

5 13. At the time of the June 10, 2013 cardiac tamponade, Ms. Tinlin had been
6 advised that the incident may affect her organs in the future. (*Id.* at 6.)

7 14. As a result of her July 31, 2013 open heart surgery, Ms. Tinlin developed
8 tracheomalacia due to the prolonged time with a breathing tube, while on life support. She
9 can no longer wear her CPAP device for sleep apnea and also cannot lay on her back
10 while sleeping causing severe sleep deprivation. (*Id.*)

11 15. As a further result of her July 31, 2013 open heart surgery, her sternum did
12 not fuse properly after the sternotomy and the bone marrow wore away. As a result, she
13 had a hole in her diaphragm. (*Id.*) This developed because of a sternal shift, where the
14 right and the left side of the rib cage move independently, rub together, and damage and
15 tear the diaphragm. This resulted in Ms. Tinlin having yet another procedure, a
16 diaphragmatic hernia surgery repair. (Ex. 1, Debra Tinlin Dep. Tr., 122:10-20, Feb. 8,
17 2017.)

18 16. To this day, laying on her back causes her to choke, gag, and cough and
19 sleeping on her side is very painful due to the skeletal deformity caused by her sternum
20 growing back together unevenly following the open heart surgery. (Ex. 3, Debra Tinlin
21 Dep., Exh. 3, at 6 (referencing medical records).)

22 17. Ms. Tinlin's implanting physician, Dr. Riebe, would have liked to have
23 known at the time of Ms. Tinlin's implantation:

24 a. Bard itself internally deemed the Recovery filter to have
25 unacceptable risks (Ex. 4, Joshua Riebe, M.D., Dep. Tr.) at 27:25-28:3);

26 b. Bard does not understand the root cause of why its filters migrate (*id.*
27 at 28:6-10);

1 c. Bard does not understand the root cause of why its filters perforate
2 (*id.* at 28:12-15);

3 d. Bard does not understand the root cause of why its filters tilt (*id.* at
4 28:18-19);

5 e. Bard does not understand the root cause of why its filters fracture (*id.*
6 at 28:22-23);

7 f. Bard did not have a good understanding of the long-term
8 performance of its IVCs filters (*id.* at 29:1-4);

9 g. If any company, including Bard, was concerned about its IVC filters'
10 migration (*id.* at 49:22-50:2; 51:7-13);

11 h. Bard was considering discontinuing the Recovery filter at the time of
12 Ms. Tinlin's implantation (*id.* at 52:8-14); and

13 i. Bard was aware of large data sets that reported issues with Recovery
14 migration (*id.* at 78:7-13).

15 18. All of the above information, not disclosed to Dr. Riebe, is important to Dr.
16 Riebe for the risk-benefit profile for IVC filters to minimize the risk to patients. This is of
17 paramount importance to him. (*Id.* at 15:18-16:7; 29:19-24.)

18 19. Dr. Riebe would have also expected Bard to have:

19 a. Completed a safety study on the Recovery filter before it began to
20 sell it (*id.* at 53:19-24);

21 b. Completed root-cause analyses for why filters were fracturing,
22 migrating, and killing people (*id.* at 59:21-24); and

23 c. Disclosed to him that the Recovery filter had a higher fatality rate
24 than numerous other available IVC filters (*id.* 61:24-64:8).

25 20. Information not known or disclosed to Dr. Riebe could not be relayed to his
26 patients, and he could not consider information unknown to him for his own analysis for a
27 proper risk-benefit decision for patient safety. (*Id.* at 25:5-16; 30:1-3; 54:1-2.)
28

1 21. If a company fails to disclose safety information to him, he cannot know
2 that information to relay it. (*Id.* at 171:22-172:6.)

3 22. Dr. Riebe would have liked to have known all of this information (*supra* at
4 ¶¶ 17a-h; 19a-b) so both he and the patient could understand the safety of the device. (*Id.*
5 at 60:2-6.)

6 23. Dr. Riebe understood that the Recovery filter was an “optional” filter, and
7 testified that he typically told his patients that a retrievable filter could also be left in
8 permanently, and may not be able to be retrieved. (*Id.* at 149:18-150:9.)

9 24. Dr. Riebe expressed no disagreement at his deposition that, in Ms. Tinlin’s
10 case, the filter did remain implanted as a permanent filter. (*Id.* at 165:2-6.)

11 25. Dr. Muehrcke testified that Ms. Tinlin is at risk of complications, including
12 arrhythmia and cardiac failure due to her filter, and explicitly agreed that this was his
13 opinion “to a reasonable degree of medical probability.” (Ex. 5, Dr. Derek Muehrcke
14 Dep. Tr., 249:15-250:10, Jan. 11, 2019.)

15 26. Dr. Muehrcke also testified that that Ms. Tinlin is at a greater risk of future
16 complications. (*Id.* at 258:10-259:3.)

17 27. Dr. Darren Hurst’s expert report states that Ms. Tinlin faces either
18 continuous monitoring and follow-up or lung resection: “These embolized arms are in
19 locations that are not amenable to percutaneous removal, and if they become symptomatic
20 will require lung resection for removal. At the least, they will require life-long follow-up
21 with CT imaging to document their stability.” (Ex. 6, Dr. Darren Hurst Dep., Exh. 3, at
22 20.)

23 28. At his deposition, Dr. Hurst testified that Ms. Tinlin will need CT imaging
24 on ongoing basis, “every year or every other year to just make sure that she’s not
25 developing an issue related to the fragments.” (Ex. 7, Dr. Darren Hurst Dep. Tr., 229:5-
26 15, Jan. 7, 2019.)

27 29. Dr. Darren Hurst’s expert report further states that Ms. Tinlin’s filter “is
28 unstable and is causing the patient multiple issues and symptoms and will need removal

1 using advanced endovascular techniques that will require referral to a specialist in
2 complex removal of these devices.” (Ex. 6, Dr. Darren Hurst Dep., Exh. 3, at 21.)

3 30. Plaintiffs’ engineering expert, Dr. McMeeking, explained in his expert
4 report that “[R]easonable alternative designs and alternative features available to Bard
5 before Mrs. Tinlin received her filter include many features that I have previously
6 identified in my reports and deposition testimony: caudal anchors, penetration limiters,
7 two-tier design, and a better (smoother and rounded) chamfer at the mouth of the “cap” on
8 the filter. Many of these design features existed in other IVC filter products already on
9 the market, including the Simon Nitinol Filter, the Cook Gunther Tulip filter, the
10 Greenfield filter, and the Cook Bird’s Nest filter.” (Ex. 8, Dr. McMeeking Expert Report,
11 Dec. 7, 2018, at 3.)

12 RESPECTFULLY SUBMITTED this 1st day of March, 2019.

13
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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of March 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine